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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,236	09/25/2006	Yoshiko Ono	47237-5011-00 (231515)	7379

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DRINKER BIDDLE & REATH (DC)
1500 K STREET, N.W.
SUITE 1100
WASHINGTON, DC 20005-1209

EXAMINER	
BETTON, TIMOTHY E	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
03/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,236	ONO ET AL.	
	Examiner	Art Unit	
	TIMOTHY E. BETTON	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7 and 21-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7 and 21-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :1 sheet, 10/26/2007; 1 sheet, 3/26/2008;1 sheet, 2/6/2009.

DETAILED ACTION

Applicants' Remarks filed on 26 March 2008 has been acknowledged and duly made of record.

Additionally, the Examiner acknowledges the entry of the Information Disclosure Statement filed on 25 September 2006. Accordingly, the Examiner acknowledges the receipt of the certified priority document.

Status of the Claims

Claims 5-7 and 21-30 are pending for further prosecution on the merits. Claims 1-4 and 8-20 are cancelled.

Rejection under 35 U.S.C. § 101

The rejection is hereby withdrawn in view of the cancellation of subject claims 13-15.

Rejection under 35 U.S.C. § 112, 1st paragraph

The rejection is hereby withdrawn in view of the dioxabicyclo [3.3.0.] octane moiety which is included in the analogue species (page 10, lines 9-27). The same moiety is the chief active component found in both sesamin and episesamin and therefore reasonably overcomes the Rejection under 35 U.S.C. § 112, 1st paragraph.

Rejection under 35 U.S.C. § 112, 2nd paragraph

The rejection is hereby withdrawn in view of the cancellation of claims 13-15

Rejection under 35 U.S.C. § 103(a)

The essence of applicants' argument is directed to the combined references alleged failure to disclose, suggest and/or teach a method comprising administering sesamin, episesamin, or an analogue thereof to augment adiponectin production, promote inducement of small adipocytes, or suppress accumulation of TNFα- producing enlarged adipocytes in the individual, as claimed. However, this disclosure constitutes functional language which holds no particular patentable weight. In other words, via the administration of sesamin and/or derivatives thereof, the one of ordinary skill would reasonably expect the same biological and physiological activity to occur in consideration of the teachings and methods of Forse et al. , Sumio et al., Keizo et al. and Kengo et al, either taken alone or in combination. Forse et al. also provides further motivation to maintain based on an essential factor in the treatment with sesamin derivatives, i.e., the lowering of TNFα- producing enlarged adipocytes in the individual. Adipocytes are already art-known to produce and secrete a number of proteins, including leptin, adipsin, properdin, and tumor necrosis factor (TNF).

Adiponectin is a protein hormone produced and secreted exclusively by adipocytes (fat cells) that regulates the metabolism of lipids and glucose. Adiponectin influences the body's response to insulin. Adiponectin also has anti-inflammatory effects on the cells lining the walls of blood vessels. High blood levels of adiponectin are associated with a reduced risk of heart attack. Low levels of adiponectin are found in people who are obese (and who are at increased risk of a heart attack).

Sumio resolves the deficiencies of Forse et al. by teaching an actual dosage by which sesamin is indicated to be of therapeutic efficacy. Keizo et al. teach sesamin derivatives in foods

and how upon oral administration activation of metabolisms directed to saccharides and lipids are effected. The one of ordinary skill would reasonably recognize the correlation between saccharide metabolism (insulin-related activity) and lipid metabolism (hypercholesterolemic activity). Kengo et al. provides the penultimate reasoning to combine based upon teaching drawn to the actual core moiety of therapeutic activity, the dioxabicyclo [3.3.0.] octane moiety.

Claim Rejection- 35 USC§ 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-7 and 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forse et al. (USPN 5,397,778), Sumio et al. (JP 06227977 A) in view of Keizo et al. (JP 11246427 A) and Kengo et al. (JP 908268887 A).

Thus, the instant claims disclose routine characterizations and properties distinct to sesamin and episesamin and, which are well-known to the skilled artisan. Sesamin and episesamin via their established mechanism of action generally induce an effect on small adipocytes, suppress the accumulation of TNF-alpha-producing enlarged adipocytes, and augmenting adiponectin.

Forse et al. teach saponin(s) containing enteral formulations for treatment of infection and inflammation. These saponin containing formulations are particularly useful in conjunction with oils rich in .omega.3 polyunsaturated fatty acids such as fish oils and flax oil but also show benefits with .omega.6 rich oils such as borage oil, black currant seed oil, canola oil and rapeseed oil. These formulations may also contain a lignan from the sesamin family.

In addition to teaching sesamin, Forse et al. also disclose episesamin (column 4, line 8).

Forse et al. teach the lowering of TNF-alpha via the administration of said agents comprising or consisting essentially of sesamin (column 6, lines 43-60).

Sumio et al. teach sesamin and/or episesamin as an active ingredient. A dose of sesamin and/or episesamin is preferably 1-100mg/day per adult daily in the case of oral administration. The purpose of claimed invention is to obtain the subject eliminating agent useful for treating ischemic reperfusion, inflammation, etc, capable of specifically catching and eliminating OH radicals, etc., having excellent safety, comprising sesamin as an active ingredient (Abstract).

Keizo et al. teach sesamin and sesamol as safe ingredients contained in food thereby upon oral administration activates the metabolisms of saccharide and lipid. The activating agent is used for prophylaxis and/or treating diseases related to abnormal lipid metabolisms such as hyperlipidemia and hypertension (Abstract).

Kengo et al. teach the base octane derivative, dioxabicyclo, from which sesame oil is purified and isolated (sesamin and/or episesamin) (Abstract).

Thus, it would be *prima facie* obvious to the skilled artisan at the time of invention to at once recognize the reasonable expectation of success with regard to a method for augmenting adiponectin production in an individual comprising administering sesamin *inter alia*, i.e., and/or derivatives or combinations thereof via the combining and incorporating together of Forse, Sumio, Keizo, and Kengo et al. The central issue of current invention is made obvious by the teachings of Forse et al., which describes embodiments drawn to sesamin and./or episesamin in association with lowering TNF-alpha. Sumio, Keizo et al., and Kengo et al. both support and suggest the motivation to combine with Forse et al. in view of subject invention. Sumio et al. teaches a specific regimen or system of oral administration. Keizo et al. teach the activation of the metabolisms of lipid. Kengo et al. teach the core structure or derivative thereof of sesamin. The skilled artisan would instantly be motivated to combine these said inventions together in view of the scope of claimed invention.

The objective evidence present in the application indicating obviousness is drawn principally to the scope of the invention which teaches the administration of sesamin, episesamin, or an analogue thereof for the comprising said moiety in an amount effective to promote inducement of small adipocytes in said individual and suppress accumulation of TNF-

alpha producing enlarged adipocytes in said individual. The objective evidence is art-known. What is this "objective evidence"? which prior art teaches this "objective evidence?" The administration of sesamin is going to reasonably induce all of the limitations as disclosed in the current claims. The functional language used to describe the activity and mechanism of action of the said composition holds no patentable significance because said functional language and/or disclosed limitations do not disclose a specific and distinct patient population.

The differences between the prior art and the claims at issue reside in the overlap of the references *supra*. However, each and every reference as disclosed teach sesamin and/or a derivative thereof and the intended use as in oral ingestion for the treatment of variable disease states which embody and encompass the diseases states of the claimed invention. These variable disease states according to the references *supra* respectively disclose: ischemic reperfusion, inflammation, activates the metabolisms of saccharide and lipid. The activating agent is used for prophylaxis and/or treating diseases related to abnormal lipid metabolisms such as hyperlipidemia and hypertension. Claims 24, 27, 24, and 30 disclose insulin resistance issues, diabetic large artery disease, coronary artery disease, and obesity, etc. The one of skill in the pertinent would readily recognize interdependence and interrelatedness of these variable disease states in view of the claimed invention and the purpose by which sesamin and derivatives thereof are incorporated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY E. BETTON whose telephone number is (571)272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/
Primary Examiner, Art Unit 1617

TEB